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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,066	03/04/2002	Preeti G. Lal	PF-0460-2 CIP	1365
27904	7590	06/29/2004	EXAMINER	
INCYTE CORPORATION EXPERIMENTAL STATION ROUTE 141 & HENRY CLAY ROAD BLDG. E336 WILMINGTON, DE 19880			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/092,066	Applicant(s) LAL ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1,4,6,8-12 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01082002</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation-in-part of U.S. Application Serial Number 09/528,959, which is a divisional of U.S. Application Serial Number 09/008,465.

Claims 1-18 are currently pending.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 2, 3, 5, 7, 13 and 14, in the reply filed on April 8, 2004 is acknowledged. The traversal is on the ground(s) that it would not constitute a serious burden to search the methods of making antibodies and methods of using the antibodies along with the compound claims. This is not found persuasive because PINCH and PINCH-ph specific polyclonal antibodies can be isolated from those naturally occurring in serum as evidenced by Rearden (Biochem. Biophys. Res. Comm. [1994] 201(3):1124-1131; 8 on form PTO-1449) B cells specific for PINCH or PINCH-ph can be isolated and used to make monoclonal antibodies by means conventional in the art.

The requirement is still deemed proper and is therefore made FINAL.

2. **Claims 1, 4, 6, 8-12 and 15-18 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 8, 2004.

Accordingly, **claims 2, 3, 5, 7 and 13-14 are the subject of examination** in the present Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3, 5, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 2, 3, 5, 13 and 14 are ultimately dependent upon non-elected claim 1 and are being examined here as if the limitations of claim 1 were physically incorporated. Claim 1 is vague and indefinite in the recitation of "human Particularly Interesting New Cyc-His protein homolog" in line 1. Applicant should correct the spelling of "Cyc" to read --Cys-- in order to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rearden (Biochem. Biophys. Res. Comm. [1994] 201(3):1124-1131; 8 on form PTO-1449).

The claims are drawn to antibodies specific for the protein disclosed in the instant specification as PINCH-PH (SEQ ID NO: 1). It is noted that PINCH-PH is 84% identical to the PINCH protein taught by Rearden and has large contiguous segments identical to the amino acid sequence of PINCH (instant specification page 7, lines 16-19 and Figures 2A-B for example).

Rearden teaches the elution of human autoantibodies specific for human PINCH from aged human red blood cells (Abstract in particular). Rearden teaches the identification of a potential autoepitope on PINCH (FKNDPYHPDHF) that shares high homology to two known autoepitopes of the red blood cell anion exchange protein (Table 2 in particular). It is noted that residues 154-164 of instant SEQ ID NO: 1 share higher homology to PINCH than PINCH does to either red blood cell anion exchange protein epitope noted by Rearden. Given the high degree of identity, not just in a single epitope, but over the entire sequence, between the PINCH protein of Rearden and the instant PINCH-PH of SEQ ID NO: 1, as well as the fact that they are all related by sequence identity to MTP, it is respectfully submitted that one skilled in the art would reasonably expect that the antibodies to PINCH will also bind to PINCH-PH. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed

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materials are different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). The prior art teaching anticipates the claimed invention.

### *Claim Rejections - 35 U.S.C. § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2, 3, 7 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rearden (Biochem. Biophys. Res. Comm. [1994] 201(3):1124-1131; 8 on form PTO-1449) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; U on form PTO-892).

Rearden et al has been discussed supra. Rearden et al does not teach monoclonal antibodies to the PINCH protein homolog of SEQ ID NO: 1. Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make antibodies specific for polypeptides comprising as fragment of the polypeptide of SEQ ID NO: 1. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and because of the potential role of PINCH proteins in the removal of old red cells as taught by Rearden. Campbell teaches the conjugation of mAbs to a toxin moiety (Figure 1.9 in particular), which constitutes both a labeling moiety [claim 13], because it allows the identification of cells to which the antibody binds, and a

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pharmaceutical agent [claim 14] because the toxin is used to eliminate a specific group of cells from a population of cells.

*Conclusion*


6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
June 21, 2004

  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER